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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,791

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JESSE1

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EXAMINER

ZHOU, SHUBO

ART UNIT

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1631

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,791	<b>Applicant(s)</b> JESSE, TACO PETER	
	<b>Examiner</b> SHUBO (Joe) ZHOU	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Amendment and Status of the Claims***

Applicant's amendment filed on 5/24/10 is acknowledged and entered.

Based on the amendment:

claims 11-14 are canceled;

claims 15-24 are newly added; and

claims 1-10 and 15-24 are pending and under consideration.

### ***Drawings***

The replacement sheet for Fig. 2 filed on 3/17/10 is acknowledged and entered.

The objection to the drawings set forth in the previous Office action is hence withdrawn.

### ***Claim Objections***

The objection to claims 1-10 set forth in the previous Office action is withdrawn in view of the amendment filed 5/24/10. Claims 4-10 have thus been examined on the merits.

### ***Claim Rejections-35 USC § 101***

The rejection to claims 11-14 under 35 U.S.C. 101 set forth in the previous Office action is withdrawn in view of the amendment filed 5/24/10, where the claims are canceled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection to claims 1-3 and 11-14 under 35 U.S.C. 112 , second paragraph, for reasons set forth in the previous Office action, is withdrawn in view of the amendment, which in turn necessitates the following rejection under the same statute.

Claims 7-10, 17-18, and 24, are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is amended to recite the method according to claim 6, “further comprising an additional pooling step.” The limitation is confusing because it’s unclear what is meant by a “pooling step,” and further it lacks antecedent basis as there appears no “pooling step” in claim 6 or the claims it depends.

Claims 8-10 and 24 are rejected for being dependent from claim 7, directly or indirectly, and thus also comprising the indefinite limitation.

Claim 9 is amended to recite the method of claim 8, “wherein the contigs are aligned using a computer program suitable for such aligning.” The limitation lacks antecedent basis as there appears no step of aligning contigs in claim 8 or in any of the claims claim 8 depends.

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The limitation “at least at least 3” recited in claim 17 and the limitation “at least at least 4” recited in claim 18 are confusing. It’s unclear whether they have different meaning than “at least 3” or “at least 4.”

Claim 24 recites the method of claim 8, “wherein the computer program is FPC.” The limitation lacks antecedent basis as there appear no reference to a computer program in claim 8 or any other claims it depends.

Clarification of the metes and bounds of the claims is requested.

### ***Claim Rejections - 35 USC § 102***

The rejection under 35 USC 102 in the previous Office action is withdrawn in view of the amendment filed 5/24/10, which, however, necessitates the following rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (Genome Research, Vol. 10, pages 789-807, 2000).

The claims are amended to be drawn to a method for providing an integrated genetic and physical map of a genome or a part thereof, the method comprising the steps of: (a) providing at least two individual genetic markers for the genome or a part thereof; in the form of a genetic map; (b) identifying at least one AFLP fragment characterizing each genetic marker by means of identified AFLP fingerprinting, employing at least one forward AFLP primer and at least one reverse AFLP primer; (c) providing a library of clones comprising fragments of the genome or a part thereof, which is an artificial chromosome library; (d) generating a multitude of pools, each pool containing a multitude of individual clones from the library; (e) generating an AFLP fingerprint for each of the pools employing forward AFLP primers and reverse AFLP primers; (f) identifying in the multitude of pools a pool in which an AFLP fragment that was identified in step (b) is present in the fingerprint of the pool; (g) generating an AFLP fingerprint for each of the individual clones in the pool identified in step (f) employing forward AFLP primers and reverse AFLP primers, and identifying the clone containing the AFLP fragment identified in step (b) in such clone's AFLP fingerprint; (h) generating a contig comprising the individual clone identified in step (g); (i) repeating steps (f)-(h) for at least a second AFLP fragment identified in step (b) whereby the second or a further AFLP fragments characterizes a second or a further genetic marker; and, (j) linking at least two contigs obtained in step (h); thereby obtaining said integrated genetic and physical map of the genome or a part thereof, which comprises

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at least two genetic markers; wherein: (1) the forward AFLP primers used in steps (b) and (e) comprise K selective nucleotides at the 3'-end of the primers, (2) the reverse AFLP primers used in steps (b) and (e) comprise L selective nucleotides at the 3'-end, (3) the forward AFLP primers used in step (g) comprise M nucleotides at the 3'-end of the primers, and (4) the reverse AFLP primers used in step (g) comprise N selective nucleotides at the 3' end, and wherein K, L, M, N are integers with a value from 0 to 10, and  $(K+L) > (M+N)$ .

In view of the indefiniteness of the claims for reasons set forth above, the art is being applied to the best interpretation of the claims as written.

As set forth in the previous Office action, Klein et al. disclose a method for using AFLP fingerprinting to link genetic markers with physical markers to generate a physical map. The method comprises providing a plurality of genetic markers including markers characterized as AFLP fragments; providing a BAC library of clones and generating a multitude of pools thereof; generating AFLP fingerprint for the pools and the clones thereof; identifying the pools and the clone containing the AFLP fragments characterizing the AFLP fragments, and generating a contig comprising the individual clones corresponding to the individual AFLP markers, wherein the forward and reverse AFLP primers used for AFLP-fingerprinting the pools and the clones are +3/+3 unique primer combinations. See at least Figs. 2-6 and pages 793, and "Methods" on pages 802-806. The steps of the method are repeated for different markers.

As noted by applicant (see page 10 of the remarks filed 3/17/10), the difference between Klein and the instant invention is that Klein does not use primers in steps (b) and

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(e), i.e. fingerprinting of individual clones, which are longer than the primers in step (g), i.e. the fingerprinting of the clones from the library. Instead, the primers used by Klein are of the same length.

Klein et al., however, explicitly disclose that their method “resulted in a low but significant error rate,” (see page 801, right column) thus inviting for changes and/or modifications of their method. Given that Klein et al. realize that primers with shorter selective nucleotides have lower selectivity and/or stringency and used shorter selective primers in the preamplification process (see page 803, left column), and given it would have been well known in the art that it would be the principle of AFLP fingerprinting that the more selective nucleotides in the primers, the higher selectivity they possess. On the other hand, because of higher selectivity, screening a library with them would have higher stringency. As a consequence, there would be some clones in some pools that would not be picked up by such high stringency, which might be one of the reasons that caused the “low but significant error rate” of Klein’s method. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Klein to use shorter primers, i.e. fewer selective nucleotides, for the fingerprinting of the clones from the library to attempt to lower the stringency and also lower the error rate. Given that Klein et al. use a large number of primer combinations (see at least page 801, left column), it would have also been obvious for one having ordinary skill in the art to try different combinations with different numbers of selective nucleotides for fingerprinting the individual clones and for screening the library, such as with a difference of at least 1, or 2 or 3, in order to obtain the optimal combination that would result in the lowest error rate.



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Klein et al. also disclose using the FPC computer program for the AFLP analysis (see page 792). They further disclose using 4-5 x genome equivalents and additional poolings. See page 793. Because Klein et al. used 4-5 x genome equivalents for pooling and generated 184 pools in total (see at least page 800, left column), it would be apparent to one having ordinary skill in the art that each pool would be around 0.02 genome equivalent, which is not more than 0.3 or 0.4 or 0.5 genome equivalents recited in the instant claims.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER